K082057

510(k) Summary of Safety and Effectiveness

FEB 2 6 2009

Submitter

Company Name: ShenZhen Dongdixin Technology Co., Ltd.
Company Contact: Zhigang Zhao
Date Summary Prepared: January 16, 2009

Device Name

Trade Name:	DX6605E-G, DX6609-G
Common Name:	TENS
Classification Name:	Trascuteneous Electrical Nerve Stimulator
Classification:	Class II

Predicate Devices (Legally Marketed Devices)

- The predicate device for the DX6605E-G and DX6609-G is the GEM-TWIN TENS, Model GM3XY/Z (GM320PT) manufactured by Genmore Technology Company, LTD. The 510(k) registration number is K042559.

Device Description

The device is a Transcuteneous Electrical Nerve Stimulator. This devices utilizes battery power to produce square wave pulsed energy through electrodes placed on the body. The device has multiple modes of application, which are software controlled by the patient. The outputs are limited by design, so that hazardous energy cannot be delivered to the patient.

Intended Use

The purpose and function of the DX6605E-G, DX6609-G device is as follows:
This device is a prescription device and only for symptomatic relief of chronic intractable pain.

. Summary of Technical Characteristics of the Device Compared to the Predicate Devices (Legally Marketed Devices)

Summary of Performance Testing: The DX6609-G (representative of the DX6605E-G) Series model has been tested to IEC60601-1-2 2nd edition, EN55011:1998+A2:2002, EN6100-3-3:1995+A1:2001 for Electrical Immunity. The device accessories were tested to ISO10993 parts 5 and 10 for cytotoxicity and skin irritation. The device was tested to IEC60601-1:1998+A1+A2:1995 for Medical Device Safety. The device was tested to IEC60601-2-10:1987+A1: 2001 and AAMI/ANSI NS-4 for product performance. The device complies with all requirements of these standards.

Conclusions

As stated above, the DX6605E-G and DX6609-G are safe and effective, comply with the appropriate medical device standards, and are substantially equivalent to the earlier identified predicate devices.

- End of Section -

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Shenzhen Dongdixin Technology Co., Ltd.
% Regulatory Technology Services, LLC
Mr. Mark Job
1394 25th Street, NW
Buffalo, Minnesota 55313

FEB 2 6 2009

Re: K082057
Trade Name: DX6605E-G and DX6609-G
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: II
Product Code: GZJ
Dated: February 10, 2009
Received: February 11, 2009

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

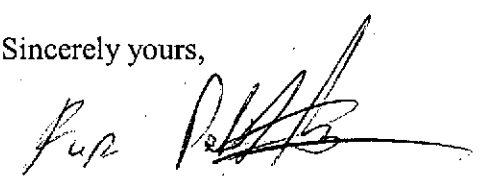
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):_____

Device Name: DX6605E-G and DX6609-G

Indications For Use:
This device is a prescription device and only for symptomatic relief of chronic intractable pain.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
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(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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